



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/549,300

01/31/2007

Lynne Canne Bannen

EX04-018C-US

3595

63572

7590

04/26/2010

MCDONNELL BOEHNEN HULBERT @ BERGHOFF LLP
300 SOUTH WACKER DRIVE
SUITE 3100
CHICAGO, IL 60606

EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

04/26/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,300	Applicant(s) BANNEN ET AL.	
	Examiner /Venkataraman Balasubramanian/	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-43,45-50 and 52-57 is/are pending in the application.
- 4a) Of the above claim(s) 25,26,29,37,38,41,45-50 and 52-57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42 is/are allowed.
- 6) ☒ Claim(s) 1,5-24,27,28,30-36,39,40 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, which included cancellation of claims 2-4, 44, 51 and amendment to claims 1, 42 and 43, filed on 01/22/2010, is made of record. Claims 1, 5-43, 45-50 and 52-57 are now pending. Of which, claims 25, 26, 29, 37, 38, 41, 45-50 and 52-57 were withdrawn from consideration in the previous office action. Claims 1, 5-24, 27, 28, 30-36, 39, 40, 42 and 43 are under consideration. In view of applicants' response, the 112 first and second paragraph rejections made in the previous office action have been obviated. In addition all 102 and 103 rejections over Heeres as well as 103 rejections over Lintz and Braje have been obviated in view of the amendment. However, the following 103 rejection made in the previous office action are maintained and in addition new grounds of rejections as necessitated by the amendment are applied to currently pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-24, 27, 28 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation of "and Y-L-Z in an ortho relationship to each other..." in currently amended claim 1 renders claim 1 and its dependent claims 5-24, 27, 28 and 43 indefinite as it is not clear with respect to what group Y-L-Z group is said to be ortho.

2. Claim 5 and its dependent claims 6-24, 27 and 28 are improper dependent claims as they all dependent on cancelled claim 4. Hence, the scope of these claims remain unknown.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5-24, 27, 28, 30-36, 39, 40 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennell et al., US 7,449,576.

Pennell teaches several piperazine compounds of formula I for treating arthritis, which include instant compounds, and composition. See column 1, formula I and note the definition of various variable groups Ar¹, HAr, R¹ and L¹. Note when Ar¹ is pyridine substituted with R², with the given definition of all other variable groups, compounds taught by Pennell include instant compounds. See column 19, formula IVa. Again with the given definition of R^{2a}, R^{2b}, R^{2c} and R^{2d}, the compounds taught by Pennell include

Art Unit: 1624

instant compounds. See figure 5C, 5I and 5J for pyridine linked piperazine compounds. See entire document for various preferred embodiments, process of making, composition and method of use. See column 31-132 for examples of various compounds made. See column 138-177 for structures of the compound tested. See compound 1062 and 1141 shown therein.

Pennell differs in not exemplifying piperazinyl-pyridine compounds wherein the pyridinyl ring is further substituted with 5 to 7-membered link with or without a linker generically embraced in compound of formula I. However, Pennell teaches equivalency of those compounds exemplified with those generically claimed. Hence, it would be obvious to one trained in the art to make the compounds of formula I including instant compounds using the teaching and guidance provided by the exemplified compounds and expect these compounds to have the use taught therein.

This rejection is same as made in the previous office action but now excludes cancelled claims and species claim 42.

Applicants' traversal to overcome this rejection is not persuasive. Applicants have argued that X groups claimed is not taught in Pennell. This is incorrect. Instant X choices include piperazine core and Pennell teaches piperazine. Contrary to applicants' urging, Pennell as pointed out above teaches pyridinyl core which can be substituted with various groups which include instant Y-L-Z of claim 1 and as well as choice of such core in claim 30. Applicants' argument that "Nor does Pennell et al. give any reason to make the necessary changes to the compounds disclosed within Pennell et al. to arrive at Applicants' claimed compounds. In fact, all of the specific compounds disclosed in

Art Unit: 1624

Pennell et al. do not have any ring structure attached to the phenyl ring which is directly bonded to the piperidiny ring, which would be required within the definition of L-Y-Z of the instant claims. One skilled in the art would not have any reasonable expectation of success by making these required changes in Pennell et al. to arrive at the compounds of the instant claims because these changes would lead to compounds with properties that one skilled in the art would not be able to predict prior to making these compounds” lacks factual support. As noted above Pennell teaches a genus of compounds which include instant compounds and Pennell teaches equivalency of those compounds with those exemplified. Hence, one trained in the art would be motivated make the genus of compounds including instant genus of compounds based guidance provided in the examples taught and expect them to have the use taught in Pennell.

Furthermore, it should be noted that instant genus as whole is too large and if applicants assert that the genus of Pennell is not adequately exemplified, then the same argument is applicable to instant genus as applicants have not exemplified all representative compounds of the genus.

Hence, this rejection is proper and is maintained.

Election/Restrictions

This application contains claims 25, 26, 29, 37, 38, 41, 45-50 and 52-57 are drawn to an invention nonelected with traverse in the reply filed on 06/26/2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Allowable Subject Matter

Claim 42 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for

Art Unit: 1624

the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624